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<p>30. Union Priority: 32 33 31</p> <p>September 29, 1988 NZ 226392 October 31, 1988 NZ 226784</p> <p>71. Applicant:</p> <p>Fisher & Paykel Ltd., Mount Wellington, Auckland, NZ</p> <p>74. Agent:</p> <p>Münzhuber, R., Dipl.-Phys., 8000 Munich; Boehmert, A., Dipl.-Ing.; Hoormann, W., Dipl.-Ing. Dr.-Ing., 2800 Bremen; Goddar, H., Dipl.-Phys. Dr.rer.nat; Liesegang, R.; Dipl.-Ing. Dr.-Ing.; Eitner, E., Dipl.-Ing., 8000 Munich; Winkler, A., Dr.rer.nat., Pat. Attorneys; Stahlberg, W.; Kunutze, W.; Kouker, L., Dr., Attorneys at Law, 2800 Bremen</p>	<p>72. Inventor:</p> <p>Zwaan, Paul; Orec, Ilija; Graeme, Charles, Mount Wellington, Auckland, NZ</p>
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54. A device for humidifying gases with a small passage volume for gases (on the order of magnitude of 50 ml) has a housing that contains water with a microporous wall that runs between the water compartment inside the envelope and the space for the gases, whereby the microporous wall is permeable for water vapor but not for liquid water, and the envelope is reinforced by a support device that also serves to direct the flow of the gases over the surface of the envelope. Inside the envelope there is a heating element that is realized in the form of a flat, wound spiral, to suppress the negative effects of gas or water vapor bubbles on the heating output.

Translator's Note: The German text is itself a translation of the English-language original NZ 226392, which has been used, as far as possible, as the basis for this version to avoid introducing potentially confusing new terminology. The changes to the description are minor. The major changes are in the claims, which have been reduced in number and rearranged.

Description

This invention relates to humidifying apparatus for gases as described in the introduction to Claim 1.

The invention has been devised particularly though not exclusively for use in providing humidified gases to a patient in a hospital in need of such humidifying gases. It is an object of the present invention to provide the user with an improved apparatus for humidifying gases.

In an apparatus for humidifying gases, with a first passageway, a water supply inlet through which, during operation water is supplied to said first passageway, a second passageway through which gases are supplied to pass over a microporous wall common to both said first passageway and said second passageway at point of use, said microporous wall being permeable to water vapor but substantially impermeable to liquid water, heating means energisable to heat said water to generate vapor pressure within said first passageway sufficient to cause passage of water vapor but not liquid water through said microporous wall, the invention teaches that the microporous wall is formed from microporous film material so that a water compartment and the first passageway are formed, and that the water compartment is essentially supported by means that mechanically reinforce the water compartment to withstand the operating pressure.

In a further aspect the invention consists in the apparatus for humidifying gases, said apparatus comprising a first passageway, a water supply inlet through which during operation water is supplied to said first passageway, a second passageway through which gases are supplied to pass over a microporous wall common to both said first passageway and said second passageway at point of use, said microporous wall being permeable to water vapor but substantially impermeable to liquid water, heating means energisable to supply heat to said water to generate vapor pressure within said first passageway sufficient to cause passage of water vapor but not liquid water through said microporous wall, characterized in that a first heat sensing device is provided adjacent to the one end of said first passageway and a second heat sensing device is provided adjacent to the other end of said first passageway.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

A preferred form of the invention and modifications thereof will now be described with

reference to the accompanying drawings in which;

Figure 1 is a schematic isometric view of the humidifying apparatus,

Figure 2 is a sectional elevation of part of a water compartment supporting means,

Figure 3 is a plan view of one surface of the water compartment supporting means shown in Figure 2,

Figure 4 is a plan view of the opposite surface of the water compartment supporting means shown in Figure 3,

Figure 5 is a plan view of the water compartment,

Figure 6 is a plan view of heating apparatus,

Figure 7 is a sectional elevation of the humidifying apparatus as shown in Figure 1, whereby some detail has been omitted for clarity,

Figure 8 is a plan view of an alternative form of microporous wall,

Figure 9 and 10 are cross sections mutually at right angles of a modified form of the invention and

Figure 11 is a schematic sketch of a microporous wall used in the humidifier shown in Figure 9 and 10.

Referring to the drawings, apparatus for humidifying gases according to the present invention comprises a hollow body generally referenced 1, preferably made of a plastic material having a gases inlet 2 and a gases outlet 3, designed to be connected to tubular gas conduits between a supply of such gases and a patient.

The body 1 is assembled from a (male) hollow casing 4 and a corresponding (female) hollow casing 5, the female member 5 having an upwardly extending edge 6 (Fig. 1) which surrounds an adjacent edge of the male member 4, enabling a gas tight seal to be made between the two members e.g. by use of an adhesive or a plastics solvent. The edge 6 of the female member 5 has a water entry tube receiving depression 7 and an electrical connection receiving depression 8 therein which in use provide access to apparatus contained within body 1 as described below. Alternatively, the male and female members may be joined perpendicular to the axis of the body rather than parallel to it, as in the case described above.

The body 1 contains water compartment supporting means combined with gases flow directing means assembled from two water compartment supporting and flow distributing inner element members 10 (Figures 3 and 4). The members 10 are connected in such a way that the pins 11 of one member 10 are inserted into the locating slots 12 of a second member 10. One of the functions of the members 10 is to provide flow directing means to direct gases flow over the outer surface of the water compartment 30.

Accordingly each member 10 has a transverse baffle member 9 seen in cross section in Figures 2 and 7, a series of radiating fins 35 on one face of a main surface 13, including a pair of intersecting fins 14 and 15 which pass over a gases flow aperture 26, and on the opposite side of main member 13 an aperture shielding baffle 17 which directs gases flow into or out of the gases flow aperture 26. Side members 22 also act in directing gases flow as will be explained further below. The resulting assembly having holes 26 coaxially aligned is shown in cross section within body 1 in Figure 7. Referring to Figures 3 and 4 a baffle 16 is provided on member 10 for mixing the gases thoroughly prior to measuring their temperature with probe 64, the purpose of which is discussed later.. Each member 10 also has mounting locators 18 and 19 (Figures 2, 3 & 7) which are designed to accommodate mounting tabs having apertures 20 and 21 on the water compartment 30 (Figure 5). The fins 35, 14 and 15 of member 10 provide structural support and rigidity to the assembled apparatus and in particular provide support for the water compartment 30 and also direct gases flow over the surfaces of the water compartment 30 as described below. Thus the free edges of the fins 35, 14 and 15 and of the side members 22 engage inner surfaces of the appropriate casing 4 or 5.

The water compartment 30 is constructed from microporous sheet material 40 having welded or sealed edges 41, 42 and 43. The microporous material 40 is substantially permeable to water vapor but substantially impermeable to liquid water and is made from, for example, PTFE (Polytetrafluoroethylene). Such sheet material is manufactured under the trade mark GOR-TEX and is available from W.L. Gore & Associates, Inc. Newark, Del., U.S.A. in various thicknesses and dimensions.

To form the microporous walled water compartment 30 the sheet material 40 is cut into a rectangular shape, folded, and the edges fixed to each other for example by injecting a plastics material about the contacting edges to produce sealed edges 41, 42 and 43. The plastics material of sealed edges 41 and 43 provide mounting means comprising tabs 20 and 21. A water entry tube 45 and electrical contacts 46 are provided in the plastics material of sealed edge 43, which are connected to heating means comprising an electrical heating element 50, located within the water compartment 30.

In the preferred form of the invention the heating element 50 is provided as a flat spirally wound element in the form of an elongated disc wound preferably from enamelled copper wire preferably with turns epoxied or otherwise bonded to each other. The reason for providing the flat spiral arrangement is that in some circumstances air, gas or water vapor can be occluded within the water compartment 30 and if parts of a heating element are in an air bubble formed by that occluded air then the heating element would heat up perhaps damaging in that area. We

have found that if a plurality of turns of wire are partially exposed to air, there is a lower likelihood of damage than if, for example, a rod-shaped heating element is used, in which complete windings are exposed to air and are therefore exposed to the risk of overheating. This is due to the fact that if a plurality of turns or windings of wire are only partly exposed to air, heat can be conducted from the areas that are exposed to the air to the areas that are in the water or to adjacent turns or windings.

Alternatively the heating element may comprise a printed circuit or etched-foil format on a rigid or preferably flexible substrate (e.g. Kanthal or Mineo types); or alternatively a semiconducting material (as for example used in PTC heaters made by Hartford Eichenauer or TDK Corporation) or a composite of insulating and conductive materials such as carbon-filled plastics or carbon-filled synthetic rubbers (e.g. Premix Oy, or Jarnak Inc respectively). These latter materials may be made into a suitable shape (e.g. a rectangle) with suitably connected metal electrodes (e.g. inserted or crimped down to opposite edges) to form a non-wound heater with suitable positive temperature coefficient of resistance to facilitate temperature measurement by resistance measurement and have some degree of temperature self-limiting due to resistance increase at elevated temperatures.

The heating element 50 may be encapsulated by or bonded to a heat sink 51, comprising a quantity of thermally conductive heat sink material, preferably metal (e.g. brass) positioned within the compartment 30. In the preferred form this is rectangular in shape with rounded edges/corners and is thermally bonded to the element with heat-bonding epoxy. The purpose of the heat sink 51 is to spread the heat evenly, further preventing hotspots.

The heat sink 51 may also provide a site for overheat sensing. In the preferred form of the invention heat sink 51 provides an electrical contact for an overheat protector (Figure 6). Figure 6 illustrates one embodiment of the heat sink and overheat protector where the heat sink 51 forms one contact, the other being formed by a sprung, preferably brass member 55 attached thermally and electrically to the heat sink with a solder having a suitable preferably low melting point, referenced 56.

Overheat protection could be provided otherwise ego by having a low melting point soldered joint or a low melting point link in the wire of the heating coil.

In order to disperse water across the element/heat sink surface under all conditions a sheath or layer(s) of absorbent material 58 may be located adjacent the heat sink 51 or element 50 within the water compartment 30. The material 58 is preferably made of cotton-based paper having superior wicking properties.

In assembling the parts to make the humidifier, the water compartment 30 is fixed to a

member 10 by placing the apertures 20 and 21 over the mounting locators 18 and 19. The second member 10 is then positioned as shown in Figure 9 with the free edges of fins 35, 13 and 14 in contact with the water compartment 30 thus providing support and resistance to bulging to the compartment 30. The pins 11 engage in the slots 12 at each end of the members 10. The water connection 45 is placed in depression 7 and the electrical connections 46 placed in depression 8. This assembly is then placed in the female casing 5 and the male casing placed over the assembly of members 10 and compartment 30 and the edge 6 of the casing 5 fixed to the male casing ego by adhesive, the adhesive also joining the two halves of the gases inlet 2 and outlet 3. As stated the free edges of pins 35, 14 and 15 baffles 17 and 9 and side members 22 contact inner faces of the casings to direct gases flow. The total assembly is seen in cross section in Figure 7.

In operation water is fed to the water compartment through water entry tube 45 and electrical power is supplied to the heating element through electrical contacts 46. Gases from a source (not shown) enter the inlet 2, where transverse baffle 9 of member 10 diverts the gases downwardly, as shown by arrow 25. The gases are then diverted through air flow hole 26 by the aperture shielding baffle 17 after which the gases contact the lower outside surface of water compartment 30, being directed over the surface of the microporous material 40 by the flow directing means comprising the fins 35, 14 and 15 (Figures 3 and 4). Having passed over the lower outside surface of the water compartment 30, gases pass around the edges of the water compartment so as to come into contact with the microporous material of the upper outside surface of the water compartment. The fins 35, 14 and 15 of the upper member 10 also direct the gas flow back over the upper outside surface of the water compartment 30 as shown by the arrows 28, directing the gas flow through upper air flow hole 26 in the upper member 10. Aperture shielding baffle 17 of the upper member 10 diverts the gases toward the gases outlet 3, as shown by arrow 29 ensuring the gases pass the temperature probe 64 behind baffle 16 of member 10. The location of the temperature probe 64 is arranged to optimize accuracy of average gas temperature measurement across the outlet part, over a wide range of airflows and passageway orientation. The temperature probe comprises for example a thermistor or other temperature measuring or indicating device.

This has the advantage that should there be overheating of the gases for any reason, the probe will transmit a suitable signal to control apparatus (not shown) which will cause appropriate operation of either the heating element or the flow of gases or otherwise to control the flow of gases water or heat so as to assist in ensuring the safe supply of humidified heated gases to a destination e.g. a hospitalized patient.

The control of heat and water supplied to the water compartment 30 is substantially in accordance with our New Zealand patent specification No. 212163 (US Patent No. 4 708 831), the contents of which are incorporated herein by reference. In addition, a second temperature probe at the gas inlet may be used to detect stationary or backwards flow of gases through the chamber by measuring the relative rise in temperature at this point and a corresponding drop in temperature at the outlet sensed by the first probe. This additional feature enables the heating and humidification of the gases to be synchronized with breathing of the patient, as well as terminating humidification when the gas flow is stopped or disconnected.

It will be seen that by the foregoing there is provided a construction in which the humidifying apparatus is kept to small dimensions. Figure 1 shows somewhat to scale that the length of the apparatus is only a few times the diameter of the inlet 2 and exit 3, thus the device may only be about five to seven times such diameter and the width may only be of the order of two to three times the diameter of the inlet 2 and exit 3 and the thickness only slightly greater than such diameter. This corresponds to a volume of only 70 ml. The water compartment and the members 10 have a volume of the order of 20 ml giving a gases space of the order of only 50 ml. Additionally because of the flat spirally wound heating element and heat sink the risk of overheating due to a single turn of such an element being exposed to an air bubble is minimized or at least reduced and an overheat sensor may be provided.

It will also be seen that because of the size and simplicity of the invention and the low cost plastics materials used, the constituent parts comprising the invention may be supplied as "throwaway" items. This is a desirable feature with regard to patient hygiene in a hospital environment.

In a slightly modified form of the invention, to form the microporous walled water chamber 30 sheet material 31 is shaped for example as shown in Figure 8 so as to be foldable along a line 32 and the two halves 33 are then fixed to each other for example by injecting a plastics material about the contacting folding edges 34.

A further modified form of the invention which is shown in Figures 9 to 11 provides for heat and moisture exchanges between a patient and a gases supply.

Referring to Figures 9 and 10, a humidifying apparatus includes a second passageway 101, which is connected to a source of gases from a ventilator or similar device from which such gases are supplied to a patient, the supplied gases being indicated by the arrow. Mounted within the second passageway 101 is a first passageway 105, and that first passageway has a wall 108 common with the second passageway, such wall comprising a microporous sheet material substantially permeable to water vapor but substantially impermeable to liquid water.

The microporous membrane wall 108 is also made from for example expanded PTFE (polytetrafluoroethylene), which sheet material is also manufactured under the trade mark GOR-TEX and is available from W.L. Gore & Associates Inc. Newart Del. U.S.A. in various thickness and pore dimensions. To assist in resisting the operating pressure, the microporous wall is covered or has incorporated therein a woven or unwoven reinforcing perhaps in the form of a lattice which might be referred to as a screen lattice (not shown). In addition the sheet material is formed into a tubular form and the tubular material 36 (Figure 11) is insert molded into a cage 37 having longitudinal 38 and circumferential bars 39 with the longitudinal joint between the longitudinal edges of the material incorporated in one of the longitudinal bars of the cage. In this way a tube is supplied which is reasonably reinforced to withstand the pressures operating yet which has areas through which the water vapor but not liquid water can pass. This is arranged by adjusting the relevant pore size, hydrophobicity and thickness of the microporous material.

Arranged at the end of the tube 108 is a hollow extension 110. A connector 112 is provided through which water is supplied from a suitable supply such as a water supply bag feeding a drip chamber and controlled substantially in accordance with our aforesaid New Zealand Patent Application No. 212163 (US Patent No. 4 708 831). The heater 113 is sealed at 106 to the first passageway 115.

Within the first passageway 105 there is provided a means for heating water conveyed into the first passageway 105 through the connector 112. Such heater 113 may be a "throw-away" or preferably a reusable heater and preferably comprises a former which has wound on it many turns of a conductive material, preferably aluminum or copper or alternatives discussed previously, to provide adequate surface area not materially less than the surface area of the microporous tube through which vapor is passed. By applying a suitable low voltage, sufficient resistance can be incorporated in the wire to provide reasonable current carrying rating and a reasonable wattage rating for the heater. The heater 113 has an extension 114 which carries a primary temperature sensor such as a thermistor 111 at the distal end of the extension 114. The extension 114 fits in the follow extension 110. A secondary thermistor 121 is provided at the incoming gases end of the apparatus and the two thermistors 111 and 121 provide information to control apparatus so as to control the temperature of the gases passing through the device.

The passageway 105 is preferably provided as a "throw away" apparatus and accordingly may be readily removed.

The above apparatus has the considerable advantage of providing a good surface area of microporous tube through which water vapor can pass but substantially no liquid water can pass and the whole apparatus contained in a tube which can be kept close to the patient, thus

avoiding difficulties with cooling of the gases after having been humidified and which may cause condensation with consequent undesirable results. Positioning the humidifier in the 'dead space' between the 'wye' and the patient can also reduce the amount of flow to be humidified, overcoming limitations placed on humidifier performance by high flows in various types of operation.

As may be seen from Figure 9, the arrangement may be provided in the stern 125 of a Y function. The arrangement shown is provided in one leg of the Y function with suitable valving (not shown but usually provided by the breathing machine) so that when the patient breathes in, the gases pass over the humidifier above described and when the patient breathes out, the exhaled gases are diverted to another branch of the Y thus reducing rebreathing by the patient of already breathed gases and restricting flow over the humidifier to one direction only.

The construction has the advantage of being relatively simple yet providing the major advantage of the microporous wall arrangement.

From previous work which we have done in arriving at a satisfactory solution to the problem of successfully utilizing the microporous wall arrangement we have found great difficulty in controlling the passage of liquid water through the microporous wall into the first passageway which of course can have deleterious results with and perhaps dangerous results for a patient. The above modified form of the present invention is directed to solving this problem in a simple yet effective manner.

Nomenclature

1	Base body
2	Gas inlet
3	Gas outlet
4	Housing part (male)
5	Housing part (female)
6	Edge
7	Depression
8	Depression
9	Baffle surface
10	Assembly
11	Pin
12	Slot
13	Surface
14	Fin
15	Fin
16	Baffle
17	Deflector
18	Locator
19	Locator
20	Aperture
21	Aperture
22	Side walls
26	Gas passage aperture
30	Water container
35	Fins
37	Cage
38	Rods
39	Rods
40	Sheet material
41	Edge
42	Edge
43	Edge
45	Water feed line

46	Electrical contacts
50	Heater means
51	Heat sink
55	Brass member
56	Solder point
58	Absorbent material
64	Temperature sensor
101	Passageway, second
105	Passageway, first
108	Wall, tubes
110	Hollow extension
111	Thermistor
112	Connector
113	Heater element
114	Extension
121	Second thermistor

Claims

1. Apparatus for humidifying gases, said apparatus comprising a first passageway, a water supply inlet through which water is in use supplied to said first passageway, a second passageway through which gases are supplied to pass over a microporous wall common to both said first passageway and said second passageway at point of use, said microporous wall being permeable to water vapor but substantially impermeable to liquid water, heating means energisable to heat said water to generate vapor pressure within said first passageway sufficient to cause passage of water vapor but not liquid water through said microporous wall, **wherein** the said microporous wall is made from microporous sheet material (40), so that a water compartment (30) and the first passageway are formed, and that the water container is supported essentially by support means which mechanically reinforce the water container to withstand the operating pressure.
2. Apparatus as claimed in Claim 1, wherein the microporous wall is formed from a microporous sheet material (40), so that a flat, watertight tube is formed, whereby the abutting, cut-out edges (41, 42, 43) are glued to each other, sealed or encapsulated.
3. Apparatus as claimed in one of the Claims 1 or 2, wherein the heater element (50) has a plurality of windings of an insulated, electrically conducting material which are located inside the water container (30) so that any air bubbles that may be present will always contact a plurality of windings, so that the likelihood that only individual windings will be encompassed by such an air bubble is eliminated or at least reduced.
4. Apparatus as claimed in Claim 3 wherein changes in resistance of said electro conductive material resulting from changes in temperature are used to generate a signal that is indicative of the temperature of said heating means (50).
5. Apparatus as claimed in Claim 3 or Claim 4 wherein said turns of the electrically conductive material are bonded together.
6. Apparatus as claimed in one of the preceding Claims 3 to 5, wherein the windings of the electrically conductive material are bonded to a heat sink (51).

7. Apparatus as claimed in one of the preceding Claims 3 to 6, wherein said electrically conductive material is copper.
8. Apparatus as claimed in anyone of the preceding claims, wherein said second passageway includes flow directing means (14, 15, 16, 17, 35) arranged to provide a tortuous path for gases to enter said apparatus and pass in divided form over said microporous wall (40) for delivery from said apparatus.
9. Apparatus as claimed in Claim 8, wherein said second passageway is made as a two element plastics passageway, an inner element within which said water compartment is mounted and an outer element containing said inner element, said inner element having central air gases entry and exit.
10. Apparatus as claimed in Claim 9 wherein said inner element comprises a pair of inner element members (4, 5) each having said water compartment support means (14, 15, 35) and said flow directing means (16, 17) as parts thereof.
11. Apparatus as claimed in Claim 10, wherein radiating members on said inner element members (14, 15, 35) function both as parts of said water compartment support means and said flow directing means.
12. Apparatus as claimed in anyone of Claims 9 to 11, wherein said outer element is provided as a male body element (4) and a female body element (5) fixed to each other on assembly.
13. Apparatus as claimed in anyone of the preceding claims, wherein said second passageway is provided with a heat sensing device (64) arranged to indicate the temperature of gases leaving the passageway, said heat sensing device being positioned close to said exit from said inner element
14. Apparatus for humidifying gases as claimed in Claim 1, wherein said heating means (50) comprises a form having wound thereon heating windings comprising a length of resistance material provided so that said wound resistance material has a surface area disposed in proximity to the surface area of said microporous wall.

15. Apparatus for humidifying gases as claimed in Claim 14 wherein said heating winding is made of copper.
16. Apparatus as claimed in any one of the preceding claims, wherein the microporous tube is molded inside the support means for the water container, whereby the longitudinal connecting seam of the microporous material (40) runs parallel to a continuous rod of the support means (38, 39) that runs all the way through in the longitudinal direction.
17. Apparatus as claimed in Claim 14 or 15 or 16, wherein the form for the heater windings carries an extension (110) that extends beyond the peripheral edge of the microporous tube and that a temperature sensor is located on the farther end of this extension.
18. Apparatus as claimed in Claim 13, wherein an additional temperature sensor is located on the end of the second passageway so that the temperature of the gases flowing into the tube can be measured, to determine the direction and magnitude of the gas flow.
19. Apparatus as claimed in anyone of Claims 14 to 18 wherein said hollow form is tubular.
20. Apparatus as claimed in any one of the preceding claims, wherein said microporous tube and/or the cage (37) and/or the heater element (50) are (optionally) realized in the form of "throwaway items".
21. Apparatus as claimed in any one of the preceding claims wherein the heater element (50) is integrated into a cage (37) in the form of a "throwaway item".
22. Apparatus as claimed in any one of the preceding claims, wherein the first and second passageways are located in a housing that is located close to the patient.
23. Apparatus for humidifying gases, said apparatus comprising a first passageway, a water supply inlet through which water is in use supplied to said first passageway, a second passageway through which gases are supplied to pass over a microporous wall common to both said first passageway and said second passageway at point of use, said microporous wall being permeable to water vapor but substantially impermeable to liquid water, heating means

energisable to heat said water to generate vapor pressure within said first passageway sufficient to cause passage of water vapor but not liquid water through said microporous wall, wherein a temperature sensor (64) is located adjacent to the one end of the first passageway (105) and a second temperature sensor (121) is located adjacent to the other end of the first passageway.

4 pages of drawings